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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/265,540	03/08/99	PARHAM	C DX0804K

EXAMINER	
HAMUD, F	
ART UNIT	**PAPER NUMBER**
1646	6

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DATE MAILED: 04/27/00

04/27/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File copy

Office Action Summary

Application No.	Applicant(s)
09/265,540	Parham et al.
Examiner	**Group Art Unit**
Fozia Hamud	1646

☒ Responsive to communication(s) filed on *Dec 28, 1999* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-20* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Notice to comply with Sequence Rules

--- *SEE OFFICE ACTION ON THE FOLLOWING PAGES* ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1*-6*, drawn to a DIRS1 protein, classified in class 530, subclass 351.

Group II. Claims 1*-6*, drawn to a DIRS2 protein, classified in class 530, subclass 351.

Group III. Claims 12*-18*, drawn to a nucleic acid encoding a DIRS1 protein, a cell comprising said nucleic acid, a fusion protein comprising DIRS1 protein and a kit comprising said nucleic acid, classified in class 536, subclass 23.5.

Group IV. Claims 12*-18*, drawn to a nucleic acid encoding a DIRS2 protein, a cell comprising said nucleic acid, a fusion protein comprising DIRS2 protein and a kit comprising said nucleic acid, classified in class 536, subclass 23.5

Group V. Claim 19 *, drawn to a method of modulating physiology or development of a cell or tissue culture cells comprising exposing said cell to an agonist or an antagonist of a DIRS1 protein, class and subclass undeterminable.

Group VI. Claim 19*, drawn to a method of modulating physiology or development of a cell comprising exposing said cell to an agonist or an antagonist of a DIRS2 protein, class and subclass undeterminable.

Group VII. Claim 20 *, drawn to a method of modulating physiology or development of a cell or tissue culture cells comprising exposing said cell with a nucleic acid

encoding a DIRS1 protein and another cytokine receptor subunit, classified in class 435, subclass 6.

Group VIII. Claim 20 *, drawn to a method of modulating physiology or development of a cell or tissue culture cells comprising exposing said cell with a nucleic acid encoding a DIRS2 protein and another cytokine receptor subunit, classified in class 435, subclass 6.

Group IX Claim 7*-1[illegible]*, drawn to an antibody to DIRS1 protein , a kit comprising said antibody, a method of purifying DIRS1 protein using said antibody and a therapeutic composition comprising said antibody with a carrier, class 530, subclass 387.1.

Group X. Claim 7*-1[illegible]*, drawn to an antibody to DIRS1 protein , a kit comprising said antibody, a method of purifying DIRS1 protein using said antibody and a therapeutic composition comprising said antibody with a carrier, class 530, subclass 387.1.

*All claims 1-20 embrace multiple patentably distinct embodiments.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV, IX-X are independent and distinct, each from the other, because they are compositions which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each material composition, which cannot be exchanged (e.g., the nucleic acid encoding a DIRS1 protein cannot be exchanged for a nucleic acid encoding a DIRS2 protein since the proteins encoded by the nucleic acids are structurally and functionally different).

Although the nucleic acid of group III encodes the protein of group I and the nucleic acid of group IV encodes the protein of group II, these nucleic acid molecules can also be used as hybridization probes or in gene therapy. The nucleic acid molecules of Groups III and IV do not encode the antibodies of groups IX and X and thus these different compositions are patentably distinct. Although the antibodies of Groups IX and X can be used to obtain the nucleic acids of Groups III and IV, they can also be used in diagnostics (e.g. as a probe in immunoassays, or in immunochromatography) or they may be used therapeutically. Furthermore, the proteins of groups I and II can be used other than to raise the antibodies of groups IX and X respectively, for instance, they can be used therapeutically or diagnostically.

Inventions III and VII, IV and VIII are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids as claimed can be in gene therapy.

Inventions I, II, IX and X are unrelated to inventions V-VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the proteins of Groups I and II, and the antibodies of Groups IX and X are neither used nor produced in any of the methods of Groups V-VIII.

Inventions III, IV and V-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they

have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acids of Groups III and IV are neither used nor produced in any of the methods of Groups V-VI.

Inventions V-VIII are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

2. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). A computer readable form (CRF) of the sequence listing was submitted. However, the CRF could not be

processed by the Scientific and Technical Information Center (STIC) for the reason(s) set forth on the attached CRF Diskette Problem Report.

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached CRF Diskette Problem Report with the reply.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8896. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1646
April 25, 2000

Prema Mertz
PREMA MERTZ
PRIMARY EXAMINER